11.0 510(k) Summary of Safety and Effectiveness

DEC 0 3 2001

This Special 510(k) submission notifies the FDA of our intention to introduce the M3560A Blood Analysis Portal System as a new module for the CMS and V24/V26 family of patient monitors.

11.1 Manufacturer/Submitter

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Quality and Regulatory Affairs Engineer

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Germany

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11.2 Establishment Registration Number

9610816

11.2 Manufacturing Site Addresses:

Philips Medizinsysteme Böblingen GmbH
Hewlett-Packard Str. 2
71034 Böblingen
Germany

AND

Diametrics Medical, Incorporated
2658 Patton Road
Saint Paul, MN 55113-1136
USA

11.3 Sterilization Site

Does not apply.

11.4 Date

November 1, 2001

11.6 Device Name, Trade Name

Proprietary Name: Component Monitoring System and V24/V26 Patient Monitor, M3560A Blood Analysis Portal System Plug-In Module

Common Name: Patient Monitor Systems, Blood Analyzer Plug-In Module

Component Classifications:

Device classification information is presented in the following table. The FDA has placed all devices with arrhythmia and alarm capability in Class III. The

Classification	Procode	Description	Tier
870.1025	MHX	Monitor, Physiological, Patient (with arrhythmia detection or alarms)	3
870.1025	DSI	Detector and Alarm, Arrhythmia	3
870.2340	DPS	Electrocardiograph	2
870.1110	DSK	Computer, Blood Pressure	2
870.1120	DXQ	Cuff, Blood Pressure	2
870.1130	DXN	System, Measurement, Blood-Pressure, Non-Invasive	2
862.1170	CGZ	Electrode, Ion-Specific, Chloride	2
862.1120	CHL	Electrode Measurement, Blood Gases	2
862.1145	JFP	Electrode, Ion-Specific, Calcium	2
862.1665	JGS	Electrode, Ion-Specific, Sodium	2
862.1600	CEM	Electrode, Ion-Specific, Potassium	2
864.6400	GKG	Hematocrit	2
862.1770	CDS	Electrode, Ion-Specific, Urea Nitrogen	2

11.7 Performance Standards

Mandatory Standards:

21 CFR Part 898 establishes a performance standard for electrode lead wires and patient cables, and for arrhythmia detectors and alarms for the procodes and device classifications contained in the system and codified at 870.1025. These components of the CMS and V24/V26 Monitor Systems are unchanged from the previous submission and remain compliant. These components were previously cleared for commercial use in Premarket Notifications K000854 (cleared April 3, 2000), K993516 (cleared November 8, 1999), K980429 (cleared September 9,1998), and K991773 (cleared June 7, 1999).

11.8 Substantial Equivalence

The CMS and V24/V26 family of patient monitors with the M3560A Blood Analysis Portal System Module is substantially equivalent to the previously cleared devices listed below:

Manufacturer	Device	Model	510(k)
Agilent Technologies	Agilent Component Monitoring System	M1175A, M1176A, M1177A	K002758
Agilent Technologies	Agilent Component Monitoring System	M1175A, M1176A, M1177A, M1205A	K001722
Agilent Technologies	Agilent Component Monitoring System	M1175A, M1176A, M1177A, M3000A M3046A	K001333
Agilent Technologies	HP Viridia Component Monitoring System	M1175A, M1176A, M1177A	K992674
Hewlett-Packard	M1032A VueLink Plug-In Module	M1032A	K923682
Diametrics Medical, Inc.	IRMA Blood Analysis System	Series 2000	K981270
Hewlett-Packard	HP Component Monitoring System	M1175A, M1176A, M1177A	K882609
i-STAT	i-STAT 200 Portable Clinical Analyzer	i-STAT 200	K940918

11.9 Modification Description

The modification in this submission is the addition of an alternate blood analysis module to the current plug-in i-STAT module as a component to the CMS and V24/V26 family of patient monitors. The proposed M3560A Blood Analysis Portal System is substantially equivalent to the Diametrics IRMA Blood Analysis System but provides a plug-in interface instead of an RS232 interface connection. Only Diametrics analysis cartridges (IRMA cartridges) are used with this module. The new M3560A Blood Analysis Portal System is also smaller than the current Diametrics IRMA Blood Analysis System and does not operate via battery power.

11.10 Intended Use

The Component Monitoring System and V24/V26 family of patient monitors is intended for the monitoring, recording, and alarming of multiple physiological parameters. The devices are indicated for use in health care facilities by healthcare professionals whenever there is a need for monitoring the physiologic parameters of adult, neonatal, and pediatric patients.

11.12 Fundamental Technology

The fundamental scientific technology employed in the operation of this device has not changed from the predicate devices [K002758 (cleared 2/22/2001), K001722 (cleared 6/30/2000), K001333 (cleared 5/17/200), K981270 (cleared 5/1/1998), and K940918 (cleared 5/10/1994)].

11.13 Design Controls

Verification, validation, and testing activities will be successfully conducted and completed prior to commercialization to establish the safety, performance, and reliability characteristics of the M3560A Blood Analysis Portal System . Testing involves system level tests, integration tests, safety tests from hazard analysis, interference testing, and hardware testing. Pass/fail criteria are based on the specifications cleared for the predicate devices to demonstrate substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 0 3 2001

Philips Medizinsysteme Böblingen GmbH
c/o Ms. Denise Haley
Philips Medical Systems, Inc.
3000 Minuteman Road
Andover, MA 01810

Re: K013624
Trade Name: Component Monitoring System and V24/V26 Patient Monitor Family with M3560A Blood Analysis Portal System Plug-in Module
Regulation Number: 21 CFR 870.1025
Regulation Name: Patient Physiological Monitor
Regulatory Class: Class III (three)
Product Code: MHX
Dated: November 1, 2001
Received: November 5, 2001

Dear Ms. Haley:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

3.1 ODE Indications for Use Statement

Indications for Use Statement

510(k) Number: K013624
(if known)

Device Name: Component Monitoring System and V24/V26 Patient Monitor family with M3560A Blood Analysis Portal System Plug-In Module

Indications for Use:

The Component Monitoring System and V24/V26 family of patient monitors is intended for the monitoring, recording, and alarming of multiple physiological parameters. The devices are indicated for use in health care facilities by healthcare professionals whenever there is a need for monitoring the physiologic parameters of adult, neonatal, and pediatric patients.

PLEASE DO NOT WRITE BELOW THIS LINE--CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

Division of Cardiovascular & Respiratory Devices
510(k) Number K013624